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REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated February 26, 2003.

Status of the Claims

Claims 1-4, 9-14, and 19-21 are pending in the application. Claims 5-8 and 15-17, which are withdrawn from consideration, have been cancelled. Claims 19 and 22 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' Specification.

The Double Patenting Rejection

The Examiner has rejected Claims 19 and 22 under the judicially created doctrine of obviousness type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,591,629 ("the '629 Patent"). The Examiner asserts that, although the conflicting claims are not identical, they are not patentably distinct from each other in that the monoclonal antibody species set forth therein is the parent molecule of the antigen binding fragment of SCH 79.08 claimed and as such the antigen binding fragment of the monoclonal antibody SCH 79.08 is an obvious variant. Moreover, the Examiner argues the SCH 79.08 antibody itself anticipates the claim in regard to the generic "monoclonal antibody capable of inducing remyelination". Applicants submit that Claim 22, directed to pharmaceutical compositions comprising antigen binding fragment of SCH 79.08, is not anticipated per se by Claim 1 of the '629 Patent. Applicants further disagree that Claim 1 of the '629 Patent anticipates Claim 19, particularly as now presented and directed to pharmaceutical composition comprising synthetic autoantibody capable of inducing remyelination of central nervous axons. Applicants point out that Claim 1 of the '629 Patent is directed specifically to "a monoclonal antibody capable of stimulating remyelination of central nervous system axons, said monoclonal antibody produced by the hybridoma having the ATCC accession No. CRL 11627", which deposited and referenced

monoclonal antibody corresponds to antibody SCH 94.03 and not to antibody SCH 79.08. In any event, the SCH 79.08 monoclonal antibody is patentably distinct per se from antigen binding fragments thereof and does not anticipate synthetic autoantibodies capable of inducing remyelination of central nervous axons, even to the extent that these may be based on the SCH 79.08 monoclonal antibody. Applicants request that the double patenting rejection be withdrawn.

The Specification Fully Enables the Claimed Invention

The Examiner has rejected claims 1-4, 9-14 and 19 under 35 U.S.C. 112, first paragraph, because the Examiner asserts that the Specification, while being enabling for methods of stimulating remyelination or treating demyelinating disease in a mammal by administering an effective amount of monoclonal antibodies that induce remyelination of central nervous system axons, the specific monoclonal autoantibodies: A2B5, SCH79.08 and synthetic monoclonal autoantibodies, monoclonal autoantibodies O1, O4, and HNK-1 are not enabled. The Examiner maintains that the specific antibody clones of antibodies O1, O4 and HNK-1 are not publicly available.

With regard to HNK-1, the Examiner notes that the Exhibit which was attached to Applicant's reply mailed November 27, 2002, became detached and was not available for the Examiner's review. Applicants attach and provide a copy of said Exhibit, demonstrating the public availability of antibody HNK-1, it being available for sale by the ATCC. Applicants submit that the HNK-1 antibody is publicly available and is, in fact, offered for sale by several sources.

Applicants again argue and assert that the O1 and O4 antibodies are publicly available and for sale. Applicants once again point to the clear evidence presented in prior responses. Specifically, Applicants have demonstrated that the O1 and O4 antibodies have been offered for sale by Roche Molecular Biochemicals, USA and are presently being distributed by Chemicon International. The sales material and technical data sheets of Chemicon clearly refer back to the Roche distributed antibodies and further clearly and solely reference the isolation of these O1 and O4 antibodies by the laboratory of Dr. Melitta Schachner, as also referenced by

Applicants in the Specification. Applicants have further provided a declaration of Dr. Moses Rodriguez stating and establishing that the O1 and O4 antibodies offered for sale by Roche Molecular Biochemicals USA (now distributed by Chemicon International as noted) are the same as the O1 and O4 antibodies provided and claimed in the instant Application.

Applicants believe that there is a misunderstanding regarding the O1 and O4 antibody nomenclature and provide clarification for the Examiner. The O1 and O4 monoclonal antibodies were generated in the laboratory of Dr. Melitta Schachner and their characteristics first reported in 1981 ("Monoclonal Antibodies (O1 to O4) to Oligodendrocyte Cell Surfaces: An Immunocytological Study in the Central Nervous System", Sommer and Schachner (1981) Developmental Biology 83,311-327), as referenced in Applicants' Specification. The O1 and O4 oligodendrocyte antigens were named and are characterized per se as antigens which are bound or recognized by these monoclonal O1 and O4 antibodies of Schachner. The Kettenmen reference cited by the Examiner at page 4 of this Action is a 1985 publication from the Schachner laboratory detailing studies with the Schachner monoclonal antibodies O1 through O11, all so named as recognizing an oligodendrocyte surface antigen. Similarly, the Bastmeyer reference cited by the Examiner at page 4 of this Action is a 1989 publication reporting studies with the Schachner O1 antibody. Recently, Applicants have further been informed that R&D Systems is also offering the Schachner O1 and O4 antibodies for commercial sale. This is presented as evidence in the attached Exhibit, which Applicants assert unequivocally refers to "Clone O1" and "Clone O4". The undersigned agent for Applicants has further confirmed by telephone conversation with Dr. Melitta Schachner that these R&D Systems antibodies correspond to the Clones O1 and O4, having received the clones directly from her laboratory and institution. The Applicants submit that the O1 and O4 antibodies as claimed are publicly available and are, in fact, offered for sale by several commercial sources. Applicants appeal to the Examiner to withdraw this rejection in view of the clear evidence provided.

In view of the foregoing remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

The 35 U.S.C. 102 Rejections

The Examiner has rejected Claim 19 under 35 U.S.C. 102(b) as anticipated by Abo et al (J. Immunol., 127:1024-1029, 1981) or American Type Culture Collection Catalog, 1992, page 435, which the Examiner asserts teach the monoclonal antibody HNK-1 and anticipate the product claim. Applicants respectfully disagree and submit that these citations and the monoclonal antibody HNK-1 do not anticipate Claim 19, particularly as now presented. These references teach a particular and specific monoclonal antibody HNK-1 hybridoma clone and do not factually anticipate or teach the pharmaceutical composition of Claim 19.

The 35 U.S.C. 112, Second Paragraph Rejection

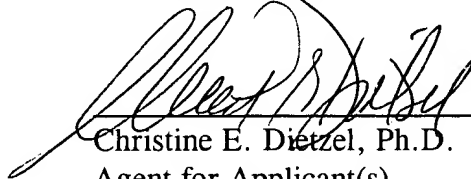
The Examiner has rejected Claim 22 under 35 U.S.C. 112, second paragraph, as indefinite in its recitation of “selected from the group”. Applicants have above amended Claim 22 to correct this error and request that the rejection be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

KLAUBER & JACKSON

A handwritten signature in black ink, appearing to read "Christine E. Dietzel", is written over a horizontal line.

Christine E. Dietzel, Ph.D.

Agent for Applicant(s)

Registration No. 37,309

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HNK-1

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Cell Lines	
ATCC Number:	TIB-200 order this item
Organism:	<i>Mus musculus</i> (B cell); <i>Mus musculus</i> (myeloma) (mouse (B cell); mouse (myeloma))
Designation:	HNK-1 [HNK1; Leu7]
Depositors:	T. Abo; C. Balch
Strain:	BALB/c (B cell); BALB/c (myeloma)
Tissue:	B lymphocyte; hybridoma
Products:	immunoglobulin; monoclonal antibody; against human natural killer (NK) cells and antigen dependent killer (K) cells (CD57)
Morphology:	lymphoblast
Comments:	<p>Animals were immunized with a membrane extract of the human lymphoblastoid cell line HSB-2.</p> <p>Spleen cells were fused with P3X63Ag8.653 myeloma cells.</p> <p>The antibody also reacts with glycoproteins present on Schwann cells, oligodendrocytes and embryonic neurons.</p> <p>Tested and found negative for ectromelia virus (mousepox).</p> <p>The cells will not grow if the medium lacks 2-mercaptoethanol.</p>
Growth Properties:	suspension
Isotype:	IgM; kappa light chain
Subculturing:	Cultures can be maintained by addition or replacement of fresh medium. Start cultures at 1×10^5 cells/ml and maintain between 1×10^5 and 1×10^6 cells/ml.
Fluid Renewal:	Every 2 to 3 days
Freeze Medium:	culture medium 95%; DMSO, 5%
References:	<p>RF10836: Abo T and Balch CM. A differentiation antigen of human NK and K cells identified by a monoclonal antibody (HNK-1). J. Immunol. 127: 1024-1029, 1981 PubMed: 81265424</p> <p>RF10837: Abo T et al. Postnatal expansion of the natural killer and killer cell population in humans identified by the monoclonal HNK-1 antibody. J. Exp. Med. 155: 321-326, 1982 PubMed: 82099947</p> <p>RF33324: Schuller-Petrovic S et al. A shared antigenic determinant between natural killer cells and nervous tissue. Nature 306: 179-181, 1983 PubMed:</p>

	84068120 RF33326: McGarry RC et al. Recognition of myelin-associated glycoprotein by the monoclonal antibody HNK-1 . Nature 306: 376-378, 1983 PubMed: 84068158 RF33406: Vincent M and Thiery JP. A cell surface marker for neural crest and placodal cells: further evolution in peripheral and central nervous system. Dev. Biol. 103: 468-481, 1984 PubMed: 84209410 RF33532: McBurney MW et al. Differentiation and maturation of embryonal carcinoma-derived neurons in cell culture. J. Neurosci. 8: 1063-1073, 1988 PubMed: 88154997 RF33539: Tucker GC et al. Identical reactivity of monoclonal antibodies HNK-1 and NC-1: conservation in vertebrates on cells derived from the neural primordium and on some leukocytes. Cell Differ. 14: 223-230, 1984 PubMed: 85024914
Propagation:	ATCC medium: RPMI 1640 medium with 2 mM L-glutamine adjusted to contain 1.5 g/L sodium bicarbonate, 4.5 g/L glucose, 10 mM HEPES, and 1.0 mM sodium pyruvate and supplemented with 0.02 mM 2-mercaptoethanol, 80%; fetal bovine serum, 20% Temperature: 37C
Related Products:	Recommended medium (without the additional supplements or serum described under ATCC Medium) -- ATCC 30-2001 recommended serum 30-2020
BioSafety Level:	1
Shipped:	Frozen
Price:	\$205.00
Revised :	Mar 05, 2001

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Cultures special ordered as test tubes, stabs or flasks, carry an additional laboratory fee of \$75.00 each. Minimum invoicing is \$45.00. Orders received for lesser amounts will be invoiced at the minimum. Terms: Net 30 from date of invoice. NO COD orders or Letters of Credit accepted. ATCC Accepts VISA, MasterCard and American Express.

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PAb=Polyclonal Antibody and MAb=Monoclonal Antibody

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Factor	Description	Catalog	Type	Size
OCAM	Mouse OCAM Affinity Purified Polyclonal Ab	AF778	Goat IgG	100 UG
OCAM	Mouse OCAM Biotinylated Affinity Purified PAb	BAF778	Goat IgG	50 UG
OCAM	Mouse OCAM MAb (Clone 125101)	MAB778	Rat IgG2A	500 UG
Oligodendrocyte Marker O1	Oligodendrocyte Marker O1 MAb (Clone O1)	MAB1327	Mouse IgM	50 UG
Oligodendrocyte Marker O4	Oligodendrocyte Marker O4 MAb (Clone O4)	MAB1326	Mouse IgM	50 UG
Omi	Human/Mouse/Rat HtrA2/Omi Affinity Purified Polyclonal Ab	AF1458	Rabbit IgG	100 UG
Oncostatin M	Mouse Oncostatin M (OSM) MAb (Clone 157210)	MAB495	Rat IgG2A	500 UG
Orexin A	Human/Mouse/Rat Orexin A Biotinylated MAb (Clone 97505)	BAM763	Mouse IgG1	250 UG
Orexin A	Human/Mouse/Rat Orexin A MAb (Clone 97505)	MAB763	Mouse IgG1	500 UG
Orexin B	Human Orexin B MAb (Clone 145202)	MAB734	Mouse IgG1	500 UG
OSM	Human Oncostatin M (OSM) Affinity Purified Polyclonal Ab	AF-295-NA	Goat IgG	100 UG
OSM	Human Oncostatin M (OSM) Biotinylated Affinity Purified PAb	BAF295	Goat IgG	50 UG
OSM	Human Oncostatin M (OSM) MAb (Clone 17001.31)	MAB295	Mouse IgG2A	500 UG
OSM	Human Oncostatin M (OSM) Polyclonal Ab	AB-295-NA	Goat IgG	1 MG
OSM	Mouse Oncostatin M (OSM) Affinity Purified Polyclonal Ab	AF-495-NA	Goat IgG	100 UG
OSM	Mouse Oncostatin M (OSM) Biotinylated Affinity Purified PAb	BAF495	Goat IgG	50 UG
OSM R beta	Mouse OSM R beta Affinity Purified Polyclonal Ab	AF662	Goat IgG	100 UG
OSM R beta	Mouse OSM R beta Biotinylated Affinity Purified PAb	BAF662	Goat IgG	50 UG
Osteocalcin	Human Osteocalcin MAb (Clone 190125)	MAB1419	Mouse IgG1	100 UG
Osteopontin	Human Osteopontin (OPN) Affinity Purified Polyclonal Ab	AF1433	Goat IgG	100 UG
Osteopontin	Human Osteopontin (OPN) MAb (Clone 190312)	MAB1433	Mouse IgG2B	100 UG
Osteopontin	Mouse Osteopontin (OPN) Affinity Purified Polyclonal Ab	AF808	Goat IgG	100 UG

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ORDERING INFORMATION

Catalog Number: MAB1327

Clone: O1

Lot Number: HWY01

Size: 50 µg

Formulation: 0.2 µm filtered solution in PBS
with 5% trehalose

Storage: -20° C

Reconstitution: sterile PBS

Specificity: human, mouse, rat and chicken
Oligodendrocyte cell surface
marker O1

Immunogen: White matter of corpus callosum
from bovine brain

Ig class: mouse IgM

Applications: Immunohistochemistry
Flow cytometry

References

1. Sommer, I. and M. Schachner, 1981, Dev. Biol. 83:311 - 327.
2. Schachner, M. *et al.*, 1981, Dev. Biol. 83:328 - 338.
3. Bansal, R. *et al.*, 1989, J. Neurosci. Res. 24:548 - 557.
4. Sontheimer, H. *et al.*, 1989, Neuron 2:1135 - 1145.
5. Hardy, R.J. and V.L. Friedrich Jr., 1996, Development 122:2059 - 2069.
6. Reynolds, R. and R. Hardy, 1997, J. Neurosci. Res. 47:455 - 470.
7. Ono, K. *et al.*, 1997, J. Neurosci. Res. 48:212 - 225.
8. Cai, Z. *et al.*, 2001, Brain Res. 898:126 - 135.
9. O1 surface antigen is a lipid that can be solubilized from the membrane by treatment with ethanol.

Monoclonal Anti-Oligodendrocyte Marker O1 Antibody

Preparation

This antibody was produced from a hybridoma resulting from the fusion of a mouse myeloma with B cells obtained from a mouse immunized with white matter of corpus callosum from bovine brain.¹ The IgM fraction of the tissue culture supernatant was purified by anti-IgM affinity chromatography.

Formulation

Lyophilized from a 0.2 µm filtered solution in phosphate-buffered saline (PBS) with 5% trehalose.

Endotoxin Level

< 0.1 EU per 1 µg of the antibody as determined by the LAL method.

Reconstitution

Reconstitute with sterile PBS. If 50 µL of PBS is used, the antibody concentration will be 1 mg/mL.

Storage

Lyophilized samples are stable for twelve months from date of receipt when stored at -20° C to -70° C. Upon reconstitution, the antibody can be stored at 2° - 8° C for 1 month without detectable loss of activity. Reconstituted antibody can also be aliquotted and stored frozen at -20° C to -70° C in a manual defrost freezer for six months without detectable loss of activity. **Avoid repeated freeze-thaw cycles.**

Specificity

Oligodendrocytes are myelinating cells in the central nervous system (CNS) that form the myelin sheath of axons to support rapid nerve conduction. The monoclonal antibody O1 reacts with a glycolipid antigen that is expressed on the surface of late oligodendrocyte progenitors. It has been commonly used in conjunction with O4 antibody to define immature oligodendrocyte.²⁻⁷ Progenitors that are O4 antigen-positive and O1 antigen-negative have been shown to differentiate into O1 antigen-positive oligodendrocytes *in vitro*.⁸

Applications

Immunohistochemistry - This antibody can be used with the appropriate secondary reagents at 1 - 3 µg/mL to detect Oligodendrocyte marker O1 in fixed cells. Cells were fixed with 4% paraformaldehyde in PBS at room temperature for 20 min., and then blocked with 10% normal donkey serum and 1% BSA in PBS at room temperature for 45 min. After blocking, cells were incubated with diluted primary antibody overnight at 4° C and then with Rodamine Red coupled anti-mouse IgM or other appropriate secondary antibody at room temperature in the dark for an hour. Between each step, cells were washed with PBS + 0.1% BSA. This antibody can also be used in unfixed, shock frozen tissue at the concentration of 5 µg/mL.⁹

Flow Cytometry - Dilute this antibody to 0.1 mg/mL and add 5 µL of this solution to 1 - 2.5 x 10⁵ cells in a total reaction volume not exceeding 200 µL. The binding of unlabeled monoclonal antibodies may be visualized by adding 10 µL of a 25 µg/mL stock solution of a secondary developing reagent such as goat anti-mouse IgM conjugated to a fluorochrome.

Optimal dilutions should be determined by each laboratory for each application.

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1-800-343-7475

5/20/03



ORDERING INFORMATION

Catalog Number: MAB1326

Clone: O4

Lot Number: HWW01

Size: 50 µg

Formulation: 0.2 µm filtered solution in PBS with 5% trehalose

Storage: -20° C

Reconstitution: sterile PBS

Specificity: human, mouse, rat and chicken Oligodendrocyte cell surface marker O4

Immunogen: White matter of corpus callosum from bovine brain

Ig class: mouse IgM

Applications: Immunohistochemistry
Flow cytometry

References

1. Sommer, I. and M. Schachner, 1981, Dev. Biol. **83**:311 - 327.
2. Schachner, M. *et al.*, 1981, Dev. Biol. **83**:328 - 338.
3. Bansal, R. *et al.*, 1989, J. Neurosci. Res. **24**:548 - 557.
4. Bansal, R. and S.E. Pfeiffer, 1989, Proc. Natl. Acad. Sci. USA **86**:6181 - 6185.
5. Gard, A. *et al.*, 1995, Dev. Biol. **167**:596 - 608.
6. Reynolds, R. and R. Hardy, 1997, J. Neurosci. Res. **47**:455 - 470.
7. Ono, K. *et al.*, 1997, J. Neurosci. Res. **48**:212 - 225.
8. Pang, Y. *et al.*, 2000, J. Neurosci. Res. **62**:510 - 520.
9. Cai, Z. *et al.*, 2001, Brain Res. **898**:126 - 135.
10. O4 surface antigen is a lipid that can be solubilized from the membrane by treatment with ethanol.

Monoclonal Anti-Oligodendrocyte Marker O4 Antibody

Preparation

This antibody was produced from a hybridoma resulting from the fusion of a mouse myeloma with B cells obtained from a mouse immunized with white matter of corpus callosum from bovine brain.¹ The IgM fraction of the tissue culture supernatant was purified by anti-IgM chromatography.

Formulation

Lyophilized from a 0.2 µm filtered solution in phosphate-buffered saline (PBS) with 5% trehalose.

Endotoxin Level

< 0.1 EU per 1 µg of the antibody as determined by the LAL method.

Reconstitution

Reconstitute with sterile PBS. If 50 µL of PBS is used, the antibody concentration will be 1 mg/mL.

Storage

Lyophilized samples are stable for twelve months from date of receipt when stored at -20° C to -70° C. Upon reconstitution, the antibody can be stored at 2° - 8° C for 1 month without detectable loss of activity. Reconstituted antibody can also be aliquotted and stored frozen at -20° C to -70° C in a manual defrost freezer for six months without detectable loss of activity. **Avoid repeated freeze-thaw cycles.**

Specificity

Oligodendrocytes are myelinating cells in the central nervous system (CNS) that form the myelin sheath of axons to support rapid nerve conduction. The monoclonal antibody O4 reacts with an unidentified antigen that appears on the surface of oligodendrocyte progenitors.^{2,3} It has been commonly used as the earliest recognized marker specific for the oligodendroglial lineage.⁴⁻⁹

Applications

Immunohistochemistry - This antibody can be used with the appropriate secondary reagents at 1 - 3 µg/mL to detect Oligodendrocyte marker O4 in fixed cells. Cells were fixed with 4% paraformaldehyde in PBS at room temperature for 20 min., and then blocked with 10% normal donkey serum and 1% BSA in PBS at room temperature for 45 min. After blocking, cells were incubated with diluted primary antibody overnight at 4° C and then with Rodamine Red coupled anti-mouse IgM or other appropriate secondary antibody at room temperature in the dark for an hour. Between each step, cells were washed with PBS + 0.1% BSA. This antibody can also be used in unfixed, shock frozen tissue at the concentration of 5 µg/mL.¹⁰

Flow Cytometry - Dilute this antibody to 0.1 mg/mL and add 5 µL of this solution to 1 - 2.5 x 10⁵ cells in a total reaction volume not exceeding 200 µL. The binding of unlabeled monoclonal antibodies may be visualized by adding 10 µL of a 25 µg/mL stock solution of a secondary developing reagent such as goat anti-mouse IgM conjugated to a fluorochrome.

Optimal dilutions should be determined by each laboratory for each application.

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